Novel Non-Ablative Approach using ClearLift™ High Power Q-Switched 1064-nm Nd:YAG Laser for Aged-Skin Repair

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Background Scientific research in the field of energy- and light-based procedures made it possible to develop a very new and innovative generation of lasers which combine the benefit of a non-ablative and a fractionated laser device promising an improved method to revitalize aging skin without harming the epidermis. With this pilot case series we performed one of the first systematic reports evaluating efficacy and safety of the non-ablative Q-Switched 1064-nm neodymium:YAG laser device in the treatment of rhytids of the face, neck and chest. **Methods** Seven healthy female subjects (Mean 53.8 ± SD 10.0) with visible signs of facial and neck skin aging were treated with non-ablative Q-Switched 1064-nm neodymium:YAG laser device (ClearLift™, Alma® Lasers). Treated areas were the face, including the periorbital and perioral regions (particularly the upper lip), neck and chest. Treatments consisted of 3 sessions at 2-4 week intervals. Follow-up was performed monthly following the final treatment. The Alexiades-Armenakas Comprehensive Grading Scale of Skin Aging was employed to assess efficacy. Pain ratings were recorded by 10-point visual assessment scoring. **Results** Employing the validated, quantitative grading scale for rhytids of the face and neck, a 0.29 grade improvement or 11.3% improvement over baseline grade was observed in the 7-subject cohort that completed follow-up following a mean of approximately 2 treatments at approximately 1 month follow-up. No pain and rapidly resolving minimal erythema were noted in all subjects during treatment. **Conclusion** The results of this pilot case series suggest that the treatment with the non-ablative Q-Switched 1064-nm Nd:YAG laser device significantly improves superficial rhytides. With its outstanding safety it seems to be particularly suitable for the treatment of sensitive areas, such as periorbital, lip, neck and chest. The Q-switched Nd:YAG laser is a facile, safe and fast treatment for improving the appearance of aged skin.

INTRODUCTION

Lasers direct a high-energy beam of a single wavelength of coherent light into specific tissues, varying in strength and the type of tissue they target[1-3] Corresponding to its chronological development two main laser classifications have been established in the past regarding the degree of ablation and recovery[7]. Ablative laser systems, e.g. CO_2 and Er:YAG lasers, were among the first resurfacing devices which were proven successful[2,3]. Although highly effective for treating photoaged skin, the demand for less ablative treatments became evident because of the high risk of unwanted side effects, e.g. scarring, infections, edema or prolonged erythema, combined with a long recovery period and painful treatment sessions. Based upon the concept of selective photothermolysis, presented by Anderson and Parrish in the early 80s, a second less-invasive treatment modality was developed, promising good results while preserving the epidermis. This non-ablative technique was based on the principle of absorption of light and the different chromophores in the skin, such as water, melanin or hemoglobin resulting in selected damage limited to the target[1]

A novel non-ablative Q-switched Nd:YAG 1064-nm laser technology is presented here, which combines the benefit of a non-ablative and a fractionated laser device: a controlled dermal wound is produced by this near-infrared wavelength, but without harming the epidermis (Figure 1). All stages of wound healing occur under the biologic protection of an intact epidermis, so that no pre- or postoperative care is necessary[4,5] Moreover the treatment is gentle, comfortable, and promises to decreases the appearance of fine lines and wrinkles by stimulating collagen growth and skin remodeling [6]. The aim of this pilot study was to evaluate efficacy and safety of this new, novel, non-ablative Q-switched 1064-nm neodymium:YAG laser device (ClearLift™, Alma® Lasers) in the treatment of the many signs of aging skin including fine lines, and wrinkles at face and neck.

Material and Methods

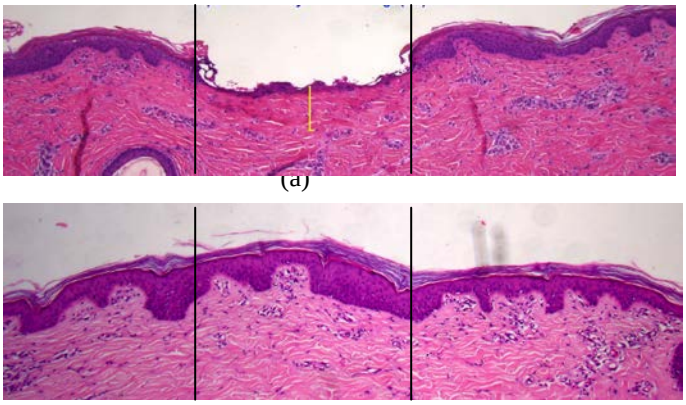
Subjects

Seven healthy female subjects, between 42 and 70 years of age (Mean 53.6 ± SD 10.0), with visible signs of facial and neck skin aging, minimum grade 2.0 on the 4.0 grading scale (The Alexiades-Armenakas Comprehensive Grading Scale of Skin Aging)[7] were enrolled. Verbal and written informed consent was obtained. The subjects were in good health and none had skin disease or took medications that would impact the skin. Women who were pregnant, planned a pregnancy, and/or nursed a child were excluded from the trial. Also individuals with a history of cosmetic treatments, e.g. botulinum toxin, hyaluronic acid, lasers, as well as surgical "cosmetic" procedures (e.g. face-lift) in the treatment area and

females that have started or changed hormone replacement therapy within 3 months from study start could not participate in the trial.

Treatment procedure

The ClearLift™, is a non-ablative, high power Q-switched 1,064nm Nd:YAG laser handpiece with a passive refractive optical element that creates a 5x5 mm matrix with 25 microscopic columns of laser-mediated effects (microcolumns) measuring ~200µm in diameter per microcolumn and high power density per pixel.



(a)

(b)

Figure 1. Fractionated ablative Pixel Er:YAG (a) vs Non-ablative Pixel QSW (ClearLift). (b). Noticeable epidermis evaporation, coagulation and secondary thermal damage (yellow line) and no rete ridges vs normal appearance of the epidermis and rete ridges, respectively.

The maximal fluence of 1200 mJ and a spot size of 5 mm were employed. The repetition rate of the laser was adjusted to 4 Hz. The ClearLift™ module is used with the Harmony^{XL} platform (Alma Lasers Ltd., Caesarea, Israel). A series of passes (8-12) were administered to each treatment area measuring approximately 20 cm^2 until the clinical endpoint of diffuse confluent erythema was attained uniformly throughout and repeated until the entire area (face, neck, or chest) was covered. Treatment of each anatomic region (eg. face, neck or chest) required approximately 20 minutes per site, totaling 400 joules per treatment area for the face (1600 joules for full face and 3600 joules total for chest. Treated areas included the face, including the periorbital and perioral regions (particularly the upper lip), neck and chest. Treatments consisted of 3 sessions at 2-4 week intervals. Follow-up was performed monthly following the final treatment.

Clinical Evaluation

The Alexiades-Armenakas Comprehensive Grading Scale of Skin Aging[7] was employed to assess efficacy. This 4-point grading scale has been extensively tested and employed for evaluating laser and energy-based cosmetic treatments. Digital photographs were taken at baseline, and at each follow up interval. Grading was conducted by the investigator at baseline and at each follow-up interval in each category following ClearLift treatment in the current study. For safety evaluations, patients were evaluated after treatment. Pain ratings using a 10-point visual assessment scoring (1=no pain, 10=worst pain ever felt) were recorded immediately upon conclusion of the treatment. Patients were instructed to monitor for side effects or complications and to follow up during the post-treatment interval should any adverse events arise. At the follow-up intervals, patients filled out post-treatment questionnaires regarding adverse events and clinical outcome.

Results

Efficacy

Seven female subjects were enrolled in this pilot case series and completed all treatment and follow-up visits. Efficacy was scored on rhytids of the face using the Alexiades-Armenakas grading scale. The mean baseline grade in rhytids across the subject population was 2.54 (± SD 0.45). The mean number of treatments was 2.57 (± SD 0.49) with a mean follow-up interval to date of 1.29 (± 0.7) months following final treatment. In the 7-subject cohort mean follow-up grade was 2.25 (± SD 0.38). The mean grade improvement was 0.29 grades or 11.3% improvement from baseline following an average of 2 treatments at the 1-month follow-up interval (Table 1 & Figure 2).

Safety

Subjects rated pain associated with the treatment immediately post-treatment using a 10-point visual assessment scale (1=no pain, 10=worst pain ever felt). The VAS pain rating was reported as 1 across the 7 trial subjects (Table 1). Immediately after the treatment, mild confluent erythema was observed in all subjects. Erythema dissipated within minutes to one hour in all subjects. In two subjects, pinpoint petechiae were observed in the infraorbital region when vascular dark circles were present pre-operatively. These petechiae resolved within 48 hours. No other adverse events were recorded. There was no incidence of edema, ecchymosis, crusting, vesiculation or dyspigmentation. No scarring was observed.

Discussion

Scientific research in the field of energy- and light-based procedures made it possible to develop a very new and innovative generation of lasers which combine the benefit of a non-ablative and a fractionated laser device promising improvements in the appearance of aging skin without harming the epidermis[4-6]. With this pilot case series we performed one of the first systematic reports evaluating efficacy and safety of the non-ablative Q-Switched 1064-nm neodymium:YAG laser device

(ClearLift™, Alma® Lasers) in the treatment of rhytids of the face, neck and chest. Employing the validated, quantitative grading scale for rhytids of the face and neck[8] a 0.29 grade improvement or 11.3% improvement over baseline grade was observed in the 7-subject cohort that completed follow-up following a mean of approximately 2 treatments at approximately 1 month follow-up. Additional improvement is expected with further follow-up intervals, as has been demonstrated with all prior non-ablative treatments.

Subject	Age	Rx#	Follow-Up (months)	Baseline	Post-Treatment	VAS
1	70	3	1	3.5	3	1
2	43	3	1	2.25	2	1
3	57	3	3	2.5	2.25	1
4	55	2	1	2.25	2	1
5	60	2	1	2.5	2.25	1
6	42	3	1	2	1.75	1
7	48	2	2	2.75	2.5	1
Mean	53.57	2.57	1.29	2.54	2.25	1
SD	10.01	0.49	0.70	0.45	0.38	0

Table 1. Demographics , VAS Scores and Rhytid Grades at Baseline and Post-Treatment with Non-Ablative Q-switched Nd:YAG (1064 nm) Laser.

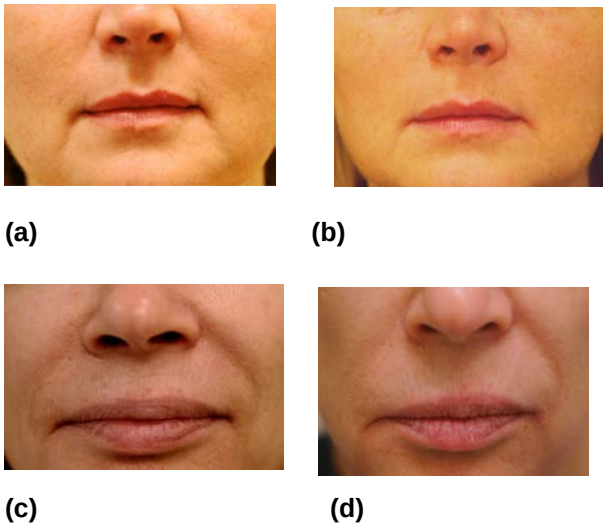
The preliminary case series presented here demonstrates that the treatment with the novel non-ablative Q-Switched 1064-nm neodymium:YAG laser device (Pixel QS Nd:YAG, Alma Lasers™) appears to be effective in the treatment of fine lines and wrinkles of the face, neck and chest with the significant advantages of being virtually painless and requiring no recovery time. Clinical outcome was observed beginning at two weeks following the first treatment and results in a less wrinkled and superiorly textured skin, especially around the eyes and perioral. Although the exact mechanism of action is not fully elucidated[9], it is generally accepted that the non-invasive induction of the dermal wound healing reaction may be the reason for the rapid responder rate[10]. This technology is based on the heating of the sub-dermal layer and the underlying extracellular matrix, which is followed by tissue contraction. This controlled thermal injury results in tissue shrinkage followed by an inflammatory response accompanied by the migration of fibroblasts into the area[11,12]. This proliferative phase is therefore characterized by an up-regulation of collagen expression (neocollagenesis/remodeling)[9], thereby resulting in contracture and tightening of the injured tissues. This newly deposited extracellular matrix may be used to strengthen the skin[13].

In years past, the Q-switched Nd:YAG (1064 nm) was employed for non-ablative laser resurfacing[14-16], however the current device presents several important technological advances that likely account for the results documented during this study. In the 1990's the Q-switched Nd:YAG (1064 nm) was employed in de-focused mode at 6-15 J/cm^2 and a 6 mm spot size for the treatment of rhytides, with mild efficacy. These reports suggested improvement in fine wrinkles and skin elasticity[4,15,17]. The focal point of the standard Q-switched Nd:YAG (1064 nm) had been designed at the skin surface, to target melanin pigment, thereby necessitating its application in defocused mode to avoid crusting and splatter. In contrast, the Q-switched Nd:YAG (1064 nm) described here has a focal point of 100 μm, just beneath the epidermis, with greater penetration in the absence of epidermal crusting. A focused delivery option of this wavelength also results in a far higher peak power of up to 130 J/cm^2 per pixel, which likely explains the achieved results with this technology. Since the wavelength is applied directly to the skin surface instead of in defocused mode, penetration depth of up to 3.5-4 mm is expected, which may also play a role in the reported outcomes here as compared to prior modalities[18].

In marked contrast to other laser devices[19-21] results show also that the treatment with the current ClearLift, Q-switched Nd:YAG (1064 nm) laser is characterized by an observed safety, even for areas with high risk of scarring such as the chest. Minimal discomfort and rapidly resolving minimal erythema were noted in all subjects during treatment. No recovery time was required. No adverse events were reported.

Conclusion

The results of this clinical study suggest that the treatment with the non-ablative Q-Switched 1064-nm neodymium:YAG laser device (ClearLift, Alma Lasers) significantly improves superficial rhytides. With its observed safety it seems to be particularly suitable for the treatment of sensitive areas, such as periorbital, lip, neck and chest. The ClearLift Q-switched Nd:YAG laser is a facile, reliable and fast approach for treating skin imperfections which is both virtually painless and without down-time.



(a) (b)

(c) (d)

Figure 2**. Before (a/c) and after (b/d) after 1 month, 2 treatments with ClearLift™ (Pixel QS Nd:YAG laser).**

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